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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,331	07/11/2003	Laurence Du-Thumm	IR 7050-00	5282

7590 04/19/2007  
Colgate-Palmolive Company  
909 River Road  
P.O. Box 1343  
Piscataway, NJ 08855-1343

EXAMINER
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KRASS, FREDERICK F

ART UNIT	PAPER NUMBER
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1614

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/19/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/618,331	<b>Applicant(s)</b> DU-THUMM ET AL.	
	<b>Examiner</b> Frederick Krass	<b>Art Unit</b> 1614	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03/14/07 (RCE Filing).
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 11, 16-18, 20-27, 29 and 31-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11, 16-18, 20-27, 29 and 31-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**Written Description Rejection (New Matter)**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11, 16-18, 20-27, 29 and 31-46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no support in the specification as originally filed for the phrase in claim 11 specifying that the enzyme "is processed" at a temperature of less than about 80 degrees Celsius. Instead, original claim 1 recited, and the specification disclosed (page 8, lines 26 and 27), "incorporating" (not processing) the enzyme into the chewable confectionary composition at a temperature of less than 80 degrees Celsius.

Accordingly, in order to obviate this ground of rejection, the examiner suggests amending the eighth and ninth lines of claim 11 to read --- wherein the enzyme has been incorporated into the chewable confectionary composition at a temperature of less than 80 degree Celsius".

### **Indefiniteness Rejection**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 29 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 28 is incomplete insofar as it depends from a canceled claim; correction is required.

### **Obviousness Rejection**

1) Claims 11, 16-18, 20-24, 26-42 and 44-46 were rejected under 35 USC 103(a) as being unpatentable over Gebresselassie et al (USP 6,379,654) in view of Wagenkencht et al (USP 4,148,872).

2) Claims 25 and 43 were rejected under 35 USC 103(a) as being unpatentable over Gebresselassie et al (USP 6,379,654) in view of Wagenkencht et al (USP 4,148,872), the combination being taken further in view of Anderson et al (USP 5,487,902).

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These rejections are maintained.

Applicant reaffirms arguments as to why it is allegedly improper to combine the teachings of these references. (Remarks, page 6, third and fourth paragraphs; remarks, page 7, third and fourth paragraphs). In response, the examiner reaffirms the responses made in the previous Office action to those arguments.

Applicant further states (remarks, page 8, second paragraph) that:

[T]he Examiner indicated that the claims would be allowable if 'factual evidence, preferably in the form of a side-by-side comparison, was provided to corroborate Applicant's allegations that the stability outlined... was indeed unexpected.' (*Final Office Action*, p.5). Applicants respectfully submit that such evidence of stability has already been provided in the disclosure of the present invention, *e.g.*, in Table III of the Specification, page 11, line 18 to page 12, line 3. Table III shows a comparison of the protease enzyme activity at 4 weeks and 8 weeks between 'Table I' (the designation for a tablet prepared in accordance with the present invention) and 'A' (a conventional tablet without enzyme); as well as a comparison between 'Table 2' (the designation for a chewing gum prepared in accordance with present invention) and 'B' (a conventional chewing gum without enzyme. It is clear from these results that the compositions of the present invention satisfy the recitation in claim 11 that 'wherein the enzyme in said chewable confectionary composition maintains its activity over at least a 4 week period when stored at 23 degrees C.

Insofar as the examiner can determine from this passage, it would appear that applicant has perhaps misunderstood the examiner's position. The examiner did not question the adequacy of support for the recitation of enzyme stability now in claim 11 as amended, nor its factual verification in the working examples. What he did question, however, was whether such stability as claimed was unexpected as compared to the prior art.

Claim 11 now requires that the enzyme "maintains its activity" over at least a 4 week period when stored at 23 degrees Celsius. Unless the prior art enzymes become completely

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inactive following storage for 4 weeks, they will meet this limitation. This issue can be obviated by inserting the term --- initial --- after “activity”.

Following such amendment, however, the claims will still fail to recite any specified degree to which activity is “maintained”; even a substantial reduction in prior art activity (so long as it was greater than zero) would continue to be read upon by the instant claim language. (This could perhaps be addressed by inserting some term equivalent in meaning to “full” before the phrase “initial activity”, keeping in mind that it should find support in the specification as originally filed). Even then, however, it will still be unclear whether the prior art enzymes would lose activity during storage as alleged by Applicant. Statements to that effect are made in the instant specification, but are not supported by any factual corroboration; there is nothing in the applied prior art which indicates that there was any problem with enzyme instability.

Applicant’s comparative examples, as discussed in the citation supra, do not provide such factual corroboration since they are not comparisons versus confectionary compositions having a water content higher than 5 percent by weight, or a composition in which the enzyme was incorporated at a temperature higher than 80 degrees Celsius. Rather, they are comparisons to compositions containing no enzyme; as such, they are not probative to the issue at hand.

### **Correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick Krass whose telephone number is (571) 272-0580. The

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examiner can normally be reached at (571) 272-0580 on Monday through Friday from 9:30AM to 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass  
Primary Examiner  
Art Unit 1614

A handwritten signature in black ink, appearing to be 'F. Krass', written over the printed name and title.